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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
CALAMITA, HEATHER	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,579	SWENSON, DAVID D.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on August 3, 2007, has been entered.

Status of Application, Amendments, and/or Claims

2. Amendments of August 3, 2007, have been received and entered in full. Claims 1-17, 33 and 34 are pending and under examination. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Mutasa et al. (Phytopathology, 1996).

With regard to claim 1, Mutasa et al. teach a method of testing the integrity of primers in a multiplex amplification reaction, the amplification reaction comprising primers sufficient to amplify at least two different target sequences, the method comprising,

a) providing in a mixture the primers sufficient to amplify at least two different target sequences and a single-stranded polynucleotide sequence comprising the sequences of each of the primers, sufficient to amplify at least two different target sequences subsequences of the primers at least five nucleotides long, or complements of the sequences of the primers (see p. 494 col. 1, under *PCR primers*, where the target DNA is the single-stranded sequence as ds DNA in a nested multiplex PCR reaction becomes single-stranded upon denaturation and the sequence comprises all of the sequences of all of the primers. For example the target contains the sequences of the forward and reverse outer primers and the sequences of the forward and reverse nested primers. Both the outer and nested primers are twenty nucleotides in length meeting the limitation of at least 5 nucleotides long. Additionally, the primers amplify two target sequences. A 1.14 kb and a 0.8 kb sequence. The outer primers amplify a target and the nested primers amplify a second target which is contained within the target sequence amplified by the outer primers.)

b) amplifying the polynucleotide sequence (see p. 494 col. 1, under *DNA amplification conditions*, where the target DNA is subjected to PCR; and

c) detecting the presence or absence of the amplified polynucleotide, thereby testing the integrity of the primers in the amplification reaction (see p. 494 col. 1, under *Sensitivity of single tube nested PCR,* where the presence or absence of the amplicons are detected using an agarose gel and are an indication of the primer integrity).

With regard to claim 2, Mutasa et al. teach wherein the target sequences are less than 50% identical to each other (see p. 495 Figure 2A and legend, where Mutasa et al. teach several different unrelated species from which the genomic DNA was extracted and contained the target within the larger genomic sequence).

With regard to claim 3, Mutasa et al. teach the single-stranded polynucleotide sequence is provided by denaturing a double-stranded polynucleotide (see p. 494 col. 1, under *DNA amplification conditions*, where the target DNA is the single-stranded sequence as ds DNA in a nested multiplex PCR reaction becomes single-stranded upon denaturation).

With regard to claim 4, Mutasa et al. teach the single-stranded polynucleotide sequence is a synthetic single-stranded polynucleotide (see p. 494 col. 1, under *DNA amplification conditions*, where the target DNA is the single-stranded sequence as ds DNA in a nested multiplex PCR reaction becomes single-stranded upon denaturation. Additionally all DNA is synthetic as the production of DNA both ex vivo and in vivo is a synthetic process).

With regard to claim 5, Mutasa et al teach the single stranded polynucleotide sequence comprises the primer sequences (see p. 494 col. 1, under *PCR primers*, where the target sequence necessarily comprises all of the primer sequences. To have successful amplification the primers must hybridize with the target sequence).

With regard to claim 6, Mutasa et al. teach the single-stranded polynucleotide sequence comprises subsequences of the primers at least five nucleotides long (see p. 494 col. 1, under *PCR primers*, where the primer sequences are 20 nucleotides in length and therefore meet the limitation of at least 5 nucleotides in length).

With regard to claim 7, Mutasa et al. teach the single-stranded polynucleotide sequence comprises all subsequences of the primers that are nine nucleotides long (s see p. 494 col. 1, under *PCR primers*, where the primer sequences are 20 nucleotides in length and therefore meet the limitation of at least 9 nucleotides in length).

With regard to claim 8, Mutasa et al. teach the single-stranded polynucleotide comprises at least two subsequences of each primer, wherein the combination of the at least two subsequences contain every nucleotide of the primer sequence (see p. 494 col. 1, under *PCR primers*, where the primer sequences are

20 nucleotides in length and the combination of two subsequences of the primers contain every nucleotide of the primer for example the target necessarily comprises the primer sequence in its entirety. For example primers having 18 nucleotides is comprised of 9 dinucleotide subsequences, therefore the single stranded polynucleotide target would comprises two dinucleotide subsequences of each primer).

With regard to claim 9, Mutasa et al. teach the single-stranded polynucleotide sequence comprises two subsequences of a primer sequence and at least the last two nucleotides of a first subsequence are identical to the first at least two nucleotides of a second subsequence (see p. 494 col. 1, under *PCR primers*, where the primer sequences are 20 nucleotides in length, where the target sequence necessarily comprises the primer sequences. For example primers having 18 nucleotides is comprised of 9 dinucleotide subsequences, therefore the single stranded polynucleotide target would comprises two dinucleotide subsequences of each primer. It is well known in the art that primers for PCR are designed to be complementary to the target sequence).

With regard to claim 10, Mutasa et al. teach at least the last five nucleotides of the first subsequence are identical to at least the first five nucleotides of the second subsequence (see p. 494 col. 1, under *PCR primers*, where the primer sequences are 20 nucleotides in length, where the target sequence necessarily comprises the primer sequences. For example primers having 20 nucleotides is comprised of four pentanucleotide subsequences, therefore the single stranded polynucleotide target would comprises two pentanucleotide subsequences of each primer. It is well known in the art that primers for PCR are designed to be complementary to the target sequence).

With regard to claim 11, Mutasa et al. teach the mixture comprises at least a first, second, and third primer and the single-stranded polynucleotide sequence comprises the sequences of the at least first, second and third primer or subsequences at least five nucleotides long of the at least first, second and third primers (see p. 494 col. 1, under *PCR primers*, where the primer sequences are 20 nucleotides in length, where the target sequence necessarily comprises the primer sequences. For example primers

having 20 nucleotides is comprised of four pentanucleotide subsequences, therefore the single stranded polynucleotide target would comprises two pentanucleotide subsequences of each primer. It is well known in the art that primers for PCR are designed to be complementary to the target sequence).

With regard to claim 13, Mutasa et al. teach the amplification of the target sequences is performed in the same reaction as the amplification of the single-stranded polynucleotide sequence (see p. 494 col. 1, under *DNA amplification conditions*, where the reaction is a nested multiplex PCR reaction and the target sequence is the single stranded polynucleotide sequence).

With regard to claim 14, Mutasa et al. teach the mixture comprises a first primer pair and the single-stranded polynucleotide sequence comprises sequences, or complement thereof, of primers of the first primer pair oriented such that the first primer pair is capable of amplifying the remaining primer sequences, or subsequences thereof, in the single-stranded polynucleotide (see p. 494 col. 1, under *PCR primers*, where the target DNA is the single-stranded sequence as ds DNA in a multiplex PCR reaction becomes single-stranded upon denaturation and the sequence comprises the sequence of the outer primers and the nested primers, and the primers are 20 nucleotides in length meeting the limitation of at least 5 nucleotides long).

With regard to claim 15, Mutasa et al. teach the mixture comprises at least a second primer pair comprising a forward and a reverse primer, wherein the single-stranded polynucleotide sequence comprises sequences or subsequences of the first primer pair and the second primer pair (see p. 494 col. 1, under *PCR primers*, where the nested multiplex PCR comprises single-stranded polynucleotide sequence which comprises the outer and nested primer sequences).

With regard to claim 16, Mutasa et al. teach the single-stranded polynucleotide sequence comprises subsequences of the primers at least five nucleotides long (see p. 494 col. 1, under *PCR primers*, where the primer sequences are 20 nucleotides in length and therefore meet the limitation of at least 5 nucleotides in length).

With regard to claim 17, Mutasa et al. teach the single-stranded polynucleotide sequence comprises all subsequences of the primers that are nine nucleotides long (see p. 494 col. 1, under *PCR primers*, where the primer sequences are 20 nucleotides in length and therefore meet the limitation of 9 nucleotides in length).

With regard to claim 33, Mutasa et al. teach the single stranded polynucleotide sequence comprises sequences or subsequences of the second primer pair oriented such that the reverse primer sequence of the second primer pair or subsequence thereof is closer to the 5' end of the polynucleotide sequence than the forward primer sequence of the second primer pair or subsequence thereof (see p. 494 col. 1, under *PCR primers*, where the nested multiplex PCR comprises single-stranded polynucleotide sequence which comprises the outer and nested primer sequences).

With regard to claim 34, Mutasa et al. teach the single polynucleotide sequence comprises the sequences of each primer of the first primer pair and the second primer pair (see p. 494 col. 1, under *PCR primers*, where the nested multiplex PCR comprises single-stranded polynucleotide sequence which comprises the outer and nested primer sequences)

Allowable Subject Matter

4. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments with respect to all the pending claims have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments are directed to rejections made over Kong et al. These rejections have been withdrawn in view of Applicant's amendments and new rejections

made over Mutasa et al. Applicant's arguments therefore are not relevant as they are drawn to the rejections over Kong et al.

Correspondence

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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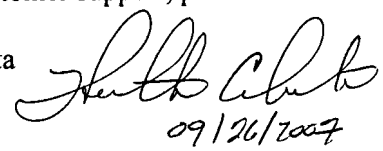
Heather Calamita
Art Unit 1637



09/26/2007